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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,025	01/29/2004	Jeffrey Marc Dayno	21311	4710

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/767,025	Applicant(s) DAYNO ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,7-10 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,11-16,18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/21/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I, drawn to a method of treating or preventing migraine in a mammalian patient comprising administering COX-2 selective inhibitor and a beta-adrenergic receptor blocking agent, classified in class 514, subclass 406 with election of etoricoxib and timolol maleate as specie of COX-2 selective inhibitor and b-adrenergic blocking agent respectively is acknowledged. The traversal is on the ground(s) that claims 1-20 can be made without any serious burden on the part of the Examiner since the inventions are sufficiently related such that they impose no serious burden on the Examiner to search and examine the application. This is not found persuasive because the claims are drawn to distinct and independent inventions as shown by the product as claimed can be used in a materially different process of using the product since the product can be use to treat cancer and serious undue burden would place on the Examiner to search different mechanisms involved in different unrelated pathways especially to search required non-patent literature search. Therefore, the restriction requirement made in the last Office Action is deemed proper and made final.

Claims 1, 2, 5, 6, 11-16 and 18 have been examined only to the extent of Applicant's election of Group I with elected species. Claims 3, 4, 7-10 and 17 are withdrawn from consideration since they are non-elected invention.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 11-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (WO 02/089798A2) and Gallagher et al. (1987).

Allen et al. teach COX-2 selective inhibitor, etoricoxib, is effective for the treatment of migraine. (abstract, page 2, lines 10-20). Allen et al. teach etoricoxib is administered at a dosage range from 10mg to about 200mg which is within Applicants claimed effective range set forth in claim 6. (page 3, lines 1-3). Allen et al. teach etoricoxib may also be administered in combination with other agents for the treatment or prevention of migraines and such administration can be concomitantly. (page 8, lines 16-20).

Allen et al. do not teach the combination with a beta adrenergic receptor blocking agent, timolol maleate and the dosage of timolol.

Gallagher et al. teach timolol maleate 10-30 mg is effective and has been shown to reduce the frequency of common migraine headaches. (abstract).

It would have been obvious to one of ordinary skill in the art to employ combinations of etoricoxib and timolol maleate for the treatment of migraine because all the components are well known individually for treating migraine. One would have been motivated to combine etoricoxib and timolol maleate for the treatment of migraine

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with a reasonable expectation of successfully treating migraine since Allen et al. teach that etoricoxib can be administered in combination with other agents concomitantly for the treatment or prevention of migraine. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)).

Claims 1, 2, 5, 6, 11-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smitchieva et al. (U.S. Patent No. 6,384,034 B2) and Gallagher et al. (1987).

Smitchieva et al. teach a composition comprising MK-663 (etoricoxib) in effective amount of about 0.1 to 500mg/kg of body weight per day for the treatment of migraine. (abstract, column 3, line 5, column 4, lines 9-14, column 1, lines 37-50, claims).

Smitchieva et al. do not teach the combination with a beta adrenergic receptor blocking agent, timolol maleate and the dosage of timolol.

Gallagher et al. teach timolol maleate 10-30 mg is effective and has been shown to reduce the frequency of common migraine headaches. (abstract).

It would have been obvious to one of ordinary skill in the art to employ combinations of etoricoxib and timolol maleate for the treatment of migraine because all the components are well known individually for treating migraine. One would have been motivated to combine etoricoxib and timolol maleate for the treatment of migraine with a reasonable expectation of successfully treating migraine since Smitchieva et al. teach that etoricoxib can be administered in combination with other agents concomitantly for the

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treatment or prevention of migraine. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
December 16, 2004

SHENGJUN WANG
PRIMARY EXAMINER